

Incidence of Hemidiaphragmatic Paralysis with Patient Controlled Infusion of Low Volume of Ropivacaine after Ultrasound Guided Low Dose Interscalene Brachial Plexus Block, A Prospective Observational Study

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Abstract

BACKGROUND Hemidiaphragmatic paralysis is a complication of single shot and continuous interscalene brachial plexus block that can be minimised by ultrasound guided extrafascial catheter placements and by limiting the amount of local anaesthetic administered. We hypothesized that patient controlled infusion of low volume of ropivacaine for a period of 24 hours would not cause hemidiaphragmatic paralysis and would provide adequate analgesia.

METHODS 54 patients aged 18-65 years undergoing surgery for shoulder dislocation or proximal humerus fracture were recruited and allocated into two groups of 27 each, patient controlled interscalene analgesia (PCIA) and multimodal analgesia (MA). Interscalene catheter was inserted at end of surgery and 10 ml of 0.5% ropivacaine was administered as single bolus dose. PCIA was initiated after four hours to deliver background infusion of 2 ml/hr, bolus of 5ml (0.2% of ropivacaine) with lockout interval of 30 minutes for a total duration of 24 hours. Incidence of hemidiaphragmatic paralysis using M-mode ultrasonography was recorded at extubation, 4, 6, 12 and 24 hrs. Numerical rating scale (NRS) for pain, patient satisfaction score and complications were also recorded. Acetaminophen (1 gm) and diclofenac 75 gm were used in MA group.

RESULT No diaphragmatic paresis was reported in patients administered the background infusion or single bolus doses of ropivacaine and scanned at 4, 6, 12 and 24 hrs. Partial paresis was noted in all patients in which two bolus doses/hour were administered 30 minutes after the second bolus. All patients with paresis had diaphragmatic excursion normalized in the next recording made at 4 hours and no complication was reported in any patient. NRS was below 3 at all time points in PCIA and the cumulative fentanyl and tramadol consumption was significantly higher in MA group. The incidence of complete and partial paresis of diaphragm was 85% and 3.7% after single shot bolus dose respectively and had resolved before start of infusion after 4 hours.

CONCLUSION Patient controlled low volume continuous infusion of ropivacaine (2 ml/hr of 0.2% of ropivacaine) with administration of a single bolus dose of 5ml in an hour does not cause unilateral phrenic paresis. Partial paresis is reported with two bolus doses/hour. Clinical trial number NCT03081728 (clinicaltrials.gov;)

Background

Hemidiaphragmatic paresis after performance of interscalene block (ISB) is secondary to the rostral spread of local anaesthetic towards the phrenic nerve (predominantly the ventral root of C4).¹ This is due to anatomical continuity of the fibrous sheath enveloping the brachial and the cervical plexus. Phrenic nerve block is associated with significant reductions in ventilatory function; 21–34% decrease in forced vital capacity (FVC), 17–37% decrease in forced expiratory volume in first second (FEV₁), and 15.4% decrease in peak expiratory flow rate (PEFR).² A reduction in both volume and concentration of local anaesthetic (10 ml of 0.25% bupivacaine) has demonstrated a reduced incidence (20%) of phrenic nerve

block.³ Use of ultrasound (US) facilitates the use of lower volumes of local anaesthetic and ensures more precise deposition of the local anaesthetic around the brachial plexus. US guided ISB performed by Renes et al. with 10 ml of 0.75% ropivacaine reported a substantially lower incidence of hemidiaphragmatic paresis (13.33%).⁴

Continuous interscalene analgesia with patient-controlled infusion of local anesthetic is the gold standard for management of pain after surgery of shoulder joint and proximal humerus. It obviates the need of supplemental opioid administration, improves sleep quality and ensures maximum patient satisfaction.⁵ The incidence of diaphragmatic paresis with continuous interscalene analgesia is 85% with catheter placements using anatomical landmark technique and is decreased to 20% in patients with catheters placed using a nerve stimulator.⁶ US guided catheter placements and reduced volume of local anaesthetics further decrease the incidence of hemidiaphragmatic paralysis.^{7,8,9} We hypothesized that patient controlled infusion of low volume of ropivacaine for a period of 24 hours would provide effective analgesia and would not cause unilateral phrenic paresis detected using M-mode [ultrasonography](#). Primary outcome was incidence of hemidiaphragmatic paresis after 24 hours and secondary outcomes included pain scores, cumulative fentanyl and tramadol requirements and incidence of adverse events in first 24 hours.

Methodology

The study was approved by PGIMER ethics committee of Postgraduate Institute of Medical Education and Research, Chandigarh, India. Written informed consent was obtained from all subjects participating in the trial. The trial was prospectively registered prior to patient enrollment at clinicaltrials.gov (NCT03081728, Principal investigator- Dr. Pankaj Kushal, Date of registration- 16/03/2017). The study was conducted in the trauma centre of our tertiary care referral hospital from April to November 2017. Patients aged 18–65 years and belonging to American Society of Anesthesiologists (ASA) physical status I-III with either fractures of the proximal humerus or shoulder dislocations were assessed for eligibility. Patients with polytrauma, head injury (GCS<15) and chronic opioid abuse were excluded from enrolment in the study.

Detailed pre-anesthetic workup was carried out in all eligible patients after their consent for participation in the study. Patients were non-randomly allocated into two groups based on the post-operative analgesic modality employed:

Group I: Patient controlled interscalene analgesia (PCIA)

Group II: Multimodal analgesia (MA).

Patients with coagulopathy, severe respiratory disease ($FEV_1/FVC < 0.7$ and $FEV_1 < 80\%$ of predicted), infection at the block site, prior history of neck surgery or radiation to the neck, associated neurological

deficit in the arm or with suspicion of nerve injury, allergy to amide local anaesthetics and inability to operate PCA were included in MA group.

Measurement of baseline diaphragmatic excursion (Group I): M-mode sonography was done in the pre-operative holding area. A low frequency curvilinear transducer (2–5 MHz, SonoSite HFL with Micro Maxx or M-Turbo, Bothell, WA, USA) placed in anterior subcostal space was used to visualize the liver/spleen and the hemi diaphragm (identified as a hyperechoic line). Diaphragmatic excursions of three respiratory cycles were imaged, values were averaged and recorded (Figure 1A).

General Anesthesia: In the operating room monitors were attached (electrocardiography (ECG), pulse oximetry and non-invasive blood pressure) and intravenous line secured. Sleep dose of propofol (2–2.5 mg/kg) and morphine (0.1 mg/kg) was administered. Ventilation by bag and mask was followed by administration of muscle relaxant (0.1 mg/kg of Vecuronium) to facilitate tracheal intubation. Maintenance of anesthesia was done with O₂/N₂O/Isoflurane (1 Minimum alveolar concentration). Post-operative pain was managed as per group allocation:

PCIA (Group I): Interscalene perineural catheter placement was done before extubation using aseptic technique. A 38 mm broadband linear array high frequency transducer (HFL 38/13–6 MHz, SonoSite Inc, Bothell, WA, USA) was placed at the level of the cricoid cartilage. C5, C6 and C7 nerve roots were visualized and an 18G epidural needle was inserted using in plane technique till the needle tip was positioned between the C6 and C7 nerve root next to the hyperechoic layer of the plexus (periplexus technique). Intravascular needle placement was ruled out by aspiration and 3–4 ml of saline was injected to hydro dissect the potential space. A non-stimulating multi-orifice catheter was advanced past the needle tip and tunneled subcutaneously in a posterior and medial trajectory below the hairline. 10 ml of 0.5% ropivacaine was administered through the catheter and spread of local anaesthetic confirmed using US.

MA (Group II) Acetaminophen (1 gm) and diclofenac 75 gm was administered before extubation in patients and subsequently continued in the post-operated period on a thrice and twice a day dosing respectively.

All patients received antiemetic prophylaxis. Neuromuscular blockade was reversed with neostigmine (50 µg/kg) and glycopyrrolate (5–10 µg/kg) after return of motor power. Patients were extubated and shifted to the PACU.

Post-operative monitoring of diaphragmatic mobility and pain management: Following parameters were recorded at Time₀(After stabilization in the PACU), Time_{POSTOPERATIVE}(4,6,12,24 hours)

- Diaphragmatic movement: Using real-time M mode ultrasonography as described above in patients in Group I and classified as:
 - Complete paralysis(Figure 1B) - if either of the below mentioned finding was seen
 - ■ ■ Reduction of more than 75% of diaphragmatic movement

- No movement
- Paradoxical movement.
- Partial paralysis- 25%–75% reduction of diaphragmatic movement
- No paresis- Less than 25% reduction of diaphragmatic movement
- Patient satisfaction visual analog score {ranging from 0 (not satisfied) to 5 (entirely satisfied)}
- Pain: Numerical rating scale ranging from 0 (no pain) to 10 (most severe pain imaginable).No intervention was done for patients with (NRS)<3. Management of pain in patients with (NRS)>3 is summarised in Figure 2.
- Post-operative complications: Nausea, vomiting, pruritus, shivering, delirium, abnormalities in vital parameters (HR, BP, SPO2) etc were recorded and managed. Patients in Group I were questioned for any clinical feature suggestive of a blockade of the phrenic nerve (breathlessness), sympathetic nerves (ptosis, miosis, anhidrosis), recurrent laryngeal nerve (hoarseness) or an accidental epidural or subarachnoid injection. Catheter dislodgements, local inflammation, pericatheter leak of local anaesthetic were recorded.

PCIA was initiated (INFUTEK 405, Simtek Medico Systems, Patel Rd, Goregaon, Mumbai, India) in patients in Group I with NRS<3 at Time_{POSTOPERATIVE(4 hours)} to deliver background infusion of 2 ml/hr, bolus of 5ml (0.2% of ropivacaine) with lockout interval of 30 minutes for a total duration of 24 hours. Patients with NRS>3 were managed as described in Figure 2.

STATISTICAL ANALYSIS

Data was analyzed using the Statistical Package for Social Science (SPSS) version 22.0. Descriptive statistics (means, standard deviation (SD), frequencies, and percentages) were used to characterize the sample. Continuous data e.g. age, weight, duration of anesthesia, heart rate (HR), mean arterial pressure (MAP), etc was expressed as mean±SD. Categorical data e.g. gender, incidence of paralysis are expressed as frequency and percentage. P value of <0.05 was considered as statistically significant and <0.001 was considered as highly significant.

Sample size calculation: Incidence of hemidiaphragmatic paralysis with continuous interscalene brachial plexus block (CISB) has been reported to be 41%. We presumed that with the low dose regime used in our study the incidence would be 30%. In order to detect this difference with an a error of 0.05 and power of 80%. Allowing for a 10% drop-out rate, we planned to recruit a total of 54 subjects. Thus a sample size of 27 for each group was selected.

Results

Enrolment of 56 patients was done and nonrandom allocation into PCIA group (29) and the MA (27) was done based on the feasibility of performance of ISB. Subsequently two patients were excluded in the PCIA group (catheter dislodgement) and the final analysis included 27 patients in each group (Figure 3).

Patient characteristics and operative details were comparable between the two groups. (Table 1).

Diaphragmatic excursions: Successfully measured in patients administered PCIA using M-mode ultrasonography both pre-operatively and in the post-operative period. The mean(SD) diaphragmatic excursion recorded in patients in the pre-operative period was 4.5 ± 0.6 cm (95% confidence interval = $4.1 - 4.9$ cm). Incidence of complete and partial paresis of diaphragm at $T_{0(\text{After stabilization in the PACU})}$ was 85% and 3.7% respectively with a mean(SD) excursion of 1.5 ± 0.8 cm (95% confidence interval = $1 - 1.9$ cm) in patients with paresis. No patient complained of breathlessness or any respiratory impairment. No patient had any diaphragmatic paresis four hours after performance of US guided ISB ($T_{\text{POSTOPERATIVE}(4 \text{ hours})}$). Partial paresis was noted in all six instances in PCIA group in which two bolus doses/hour were administered but diaphragmatic excursion normalized in the next subsequent recordings. No paresis was reported in patients administered the background infusion or single bolus doses of ropivacaine and scanned at 30 minutes after bolus and at 4, 6, 12 and 24 hrs.

Postoperative pain: NRS was significantly lower in the PCIA group at $T_{0(\text{After stabilization in the PACU})}$; 0.7 ± 1.2 (PCIA) vs 4.4 ± 1.9 (MA); $P = 0.01$. All patients in Group II were administered a single bolus dose of iv fentanyl ($0.5 \mu\text{g/kg}$) in the PACU. NRS was less than 3 and comparable in both the groups at four hours. Table 2 summarizes the value of NRS in the postoperative period. A single PCA bolus dose was administered by 13 patients (48%) in time interval 4–6 hours, 10 patients in subsequent 6–12 hrs and 10 patients in the remaining 12–24 hrs. Two bolus doses in an hour were administered by 2 patients in time interval 4–6 hours and only one patient took two bolus doses/hour in the next 6 hours. Cumulative Tramadol consumption (24 hours) was significantly (p value = 0.01) less in group I (66.6 ± 25.8 mg in PCIA vs 142.1 ± 18.1 mg in MA).

Patient Satisfaction Score: Was significantly better in PCIA at $T_{0(\text{After stabilization in the PACU})}$ and at $T_{\text{POSTOPERATIVE}(24 \text{ hours})}$ (4.0 ± 0.67 vs 3.2 ± 0.91 (mean \pm SD) in PCIA and MA respectively; $p = 0.02$).

Post-operative complications: No episodes of vomiting, respiratory discomfort, Horner's syndrome (ptosis, anhidrosis, miosis, pseudoeuphthalmos, loss of ciliospinal reflex, bloodshot conjunctiva), pneumothorax, local anaesthetic systemic toxicity (LAST) or intravascular injections. There were no complications or complaints related to the equipment. There was no pericatheter leakage or soakage of the dressing. No hematoma or inflammation or infection was detected on removal of the catheter. Patients were re-assessed 24 hours after removal of the catheter for hematoma, infection paresthesia or motor weakness.

Post-operative hemodynamic parameters were compared with the baseline values in each group (Table 3). Statistically significant increase was recorded in the heart rate in PCIA and in heart rate, mean arterial pressure and respiratory rate in MA. The value of post-operative heart rate was significantly higher in group II (91.6 ± 8.2 in PCIA vs 95.3 ± 12.6 in MA; $P = .00$)

Discussion

Patient controlled interscalene analgesia with a background infusion of 0.2% ropivacaine at a rate of 2ml/hr and a single bolus dosing of 5ml of 0.2% ropivacaine in an hour for a period of 24 hours does not cause diaphragmatic paresis. It is effective for management of post-operative pain in patients undergoing PHILOS/Hemiarthroplasty. Partial paresis is seen using M mode ultrasonography when two bolus doses are administered in an hour.

This is in contrast to previous study in which the incidence of hemidiaphragmatic paresis on POD 1 was 15% (95% CI 5–32%) when interscalene catheters were bolus dosed with 20 ml of 0.5% ropivacaine before surgery, followed by an infusion of ropivacaine 0.2% at 4 ml h⁻¹ with patient-controlled boluses of 4 ml available every 30 min for the first 2 days.¹⁰ Our study is the first to propose a drug dosing regimen of the local anaesthetic in CISB which minimises the chances of hemidiaphragmatic paresis and provides adequate pain relief.

There has been no doubt that continuous interscalene block (CISB) provides superior analgesia, compared with single-injection interscalene block, for up to 48 h after major shoulder surgery but the importance of CISB-related changes in respiratory indices has always been questionable.¹¹ This study highlights the fact that the limitations faced by the clinicians due to phrenic nerve block can be avoided by choosing lower doses.

Results of our study are comparable to those of Cuvillon et al¹² who used ultrasound for interscalene catheter placement and measurement of diaphragmatic excursion and concluded that continuous ISB did not significantly prolong the unilateral phrenic paresis after a single bolus dose. In our study eighty five percent of patients developed complete ipsilateral diaphragmatic paresis and 3.7% developed partial paresis after a single bolus dose of 10 ml of 0.5% ropivacaine but none reported any clinical features suggestive of a respiratory compromise and the diaphragmatic excursions approximated the baseline values by the end of four hours. Cuvillon et al¹² however had used higher doses; 15ml of 0.5% ropivacaine bolus followed by continuous infusion of 0.2% ropivacaine @ 5ml/hr for 48hrs.

Sinha et al¹³ reported diaphragmatic paresis in 93% of patients administered 10ml of 0.5% ropivacaine using USG-guided interscalene block. In this study we report a lower incidence (85%) which can be partly explained by the difference in the technique used i.e. extrafascial injections at C6-C7.

Hartrick et al¹⁴ administered various volumes (5, 10, 20ml) of 0.75% ropivacaine as a bolus in patients receiving continuous infusion (0.2% ropivacaine @ 4ml/hr) following arthroscopic shoulder surgery. Clinically significant dyspnea (33%) was reported in patients receiving 20ml volume with significant diaphragmatic impairment. Higher pain scores were seen in patients receiving 5ml volume. Thus, we have used 10 ml of 0.5% ropivacaine in our study as the initial bolus dose. Authors have described the minimum effective volume of local anaesthetic (0.75% ropivacaine) for shoulder analgesia in 95% patients for US-guided administrations at the C7 root level as 3.6 ml.¹⁵ This dose does not lead to hemidiaphragmatic paralysis but its analgesic efficacy needs further evaluation.

Continuous interscalene nerve blocks are not popular among the anaesthesiologists due to high catheter failure placement rate.^{6,16} The incidence in our study was 6.8%. Sakae et al¹⁷ has reported extended duration of blockade(1408 vs 1111 mins) and significant reduction in VAS scores at 24hrs post surgery with 4 mg dexamethasone as an adjuvant to ropivacaine for ultrasound-guided ISB. However we do not recommend the same as corticosteroid mediated neuro-toxicity is known and long term follow up is thus necessary for detecting complication rate and assessing safety.

Limitations of this study are that it was an observational trial in which blinding and random allocation was not done. Comparison of diaphragmatic excursion in controls was not done. Potential for inter observer variability in distance measurements using on-screen caliper tool was not excluded as evaluation of the reproducibility of these measurements was not done. Results of this study relate only to interscalene block performed for analgesic purposes and may not apply for surgical anaesthesia.

Conclusion

We conclude that patient controlled interscalene analgesia with a background infusion of 0.2% ropivacaine at a rate of 2ml/hr and a single bolus dosing of 5ml of 0.2% ropivacaine in an hour for a period of 24 hours does not cause diaphragmatic paresis. Ultrasound guided interscalene brachial plexus block at C6-C7 root using 10ml of 0.5% ropivacaine causes diaphragmatic paresis in 85% patients which is resolved by 4 hours. Thus, hemidiaphragmatic paresis should not be considered as a complication of interscalene block as it has been considered in contemporary literature in regional anaesthesia rather it should be thought of an expected sequelae which can be decreased and then eliminated by the use of lower volumes of local anaesthetics placed outside brachial plexus sheath using ultrasound guidance.

Glossary

ASA- American society of Anaesthesiology

BA- bronchial asthma

CAD- coronary artery disease

CISB - Continuous interscalene block

DM- diabetes mellitus

GA - General anaesthesia

HR - Heart rate

ISB - Interscalene block

LA - Local anaesthetic

MAC - Minimum alveolar concentration

MAP - Mean arterial blood pressure

MA - Multimodal analgesia

NPO - Nil per oral

NRS - Numerical rating scale

PCA - Patient controlled analgesia

PACU - Post anaesthesia care unit

PHILOS-Proximal humerus internal locking system

RR- respiratory rate

SP02 - Oxygen saturation

USG - Ultrasound

VAS - Visual analogue scale

Declarations

- Ethics approval and consent to participate- The study was approved by Institute ethics committee (IEC) and written informed consent was obtained from all subjects participating in the trial. The trial was prospectively registered prior to patient enrollment at clinicaltrials.gov (NCT03081728, Principal investigator- Dr. Pankaj, Date of registration- 16/03/2017)
 - Consent for publication- not applicable
 - Availability of data and materials- The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
 - Competing interests- none
 - Funding- none
 - Authors' contributions- all authors have read and approved the manuscript.
1. PK- This author helped perform the literature search, data extraction, and statistical analysis, design the study, draft and critically revise the manuscript, interpret the results, and perform a critical review of the manuscript for intellectual content.

2. TS- This author helped perform the literature search and data extraction, design the study, draft the manuscript, critically revise the manuscript, interpret the results, and perform a critical review of the manuscript for intellectual content.
3. VS- This author helped draft the manuscript, critically revise the manuscript, interpret the results, and perform a critical review of the manuscript for intellectual content.
4. SS- This author helped, critically revise the manuscript, interpret the results, and perform a critical review of the manuscript for intellectual content.
5. DKC- This author helped, critically revise the manuscript, interpret the results, and perform a critical review of the manuscript for intellectual content.
6. RK- This author helped, critically revise the manuscript, interpret the results, and perform a critical review of the manuscript for intellectual content.

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Figures

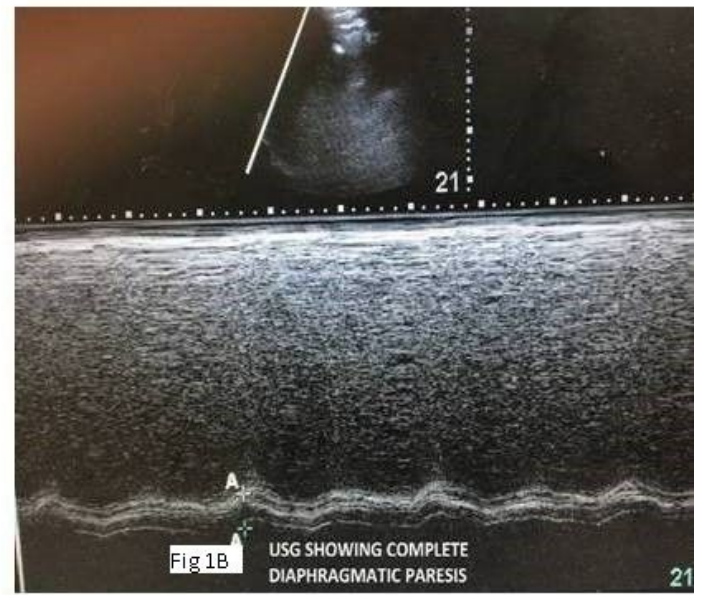
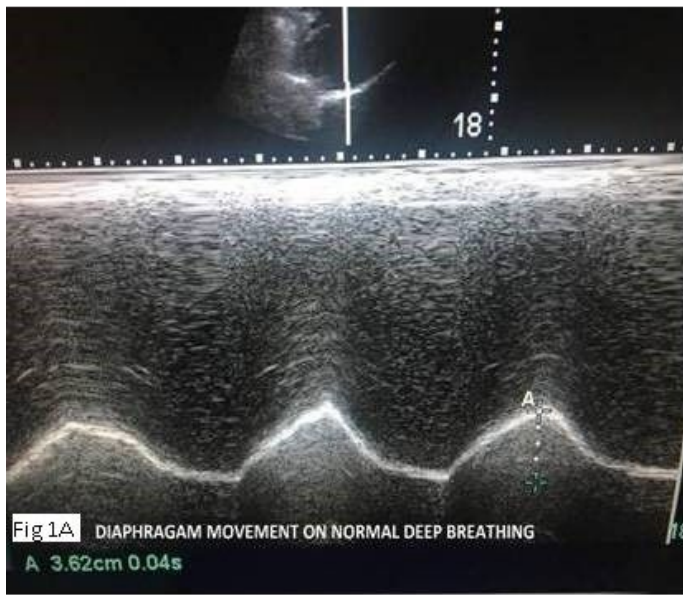
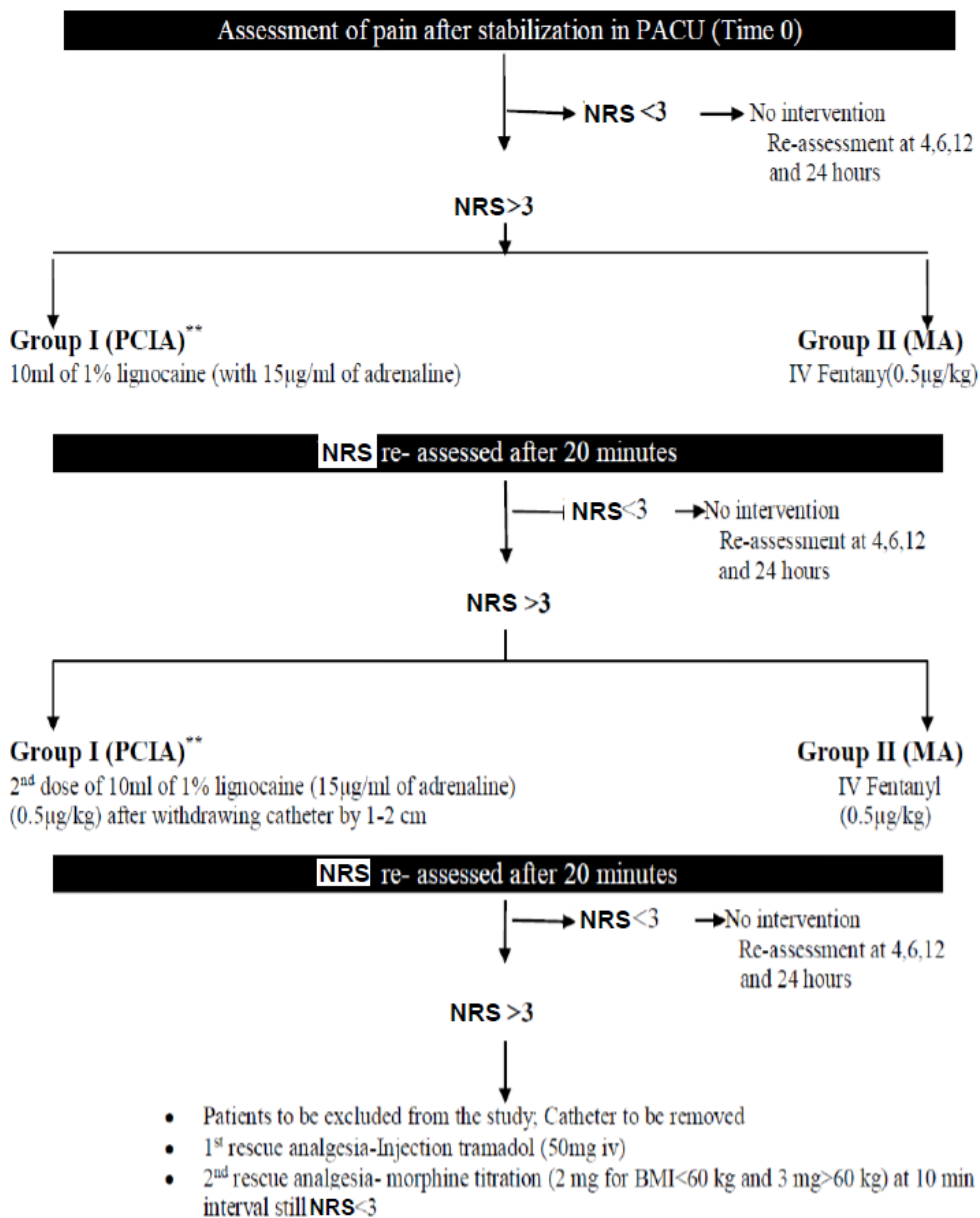


Figure 1

Diaphragmatic mobility evaluated by real-time M mode ultrasonography

Figure 2: Post-operative pain management



**PCIA was initiated after four hours of surgery

PCIA- patient controlled interscalene analgesia

MA- multimodal analgesia

NRS - numerical rating scale

Figure 2

Post-operative pain management

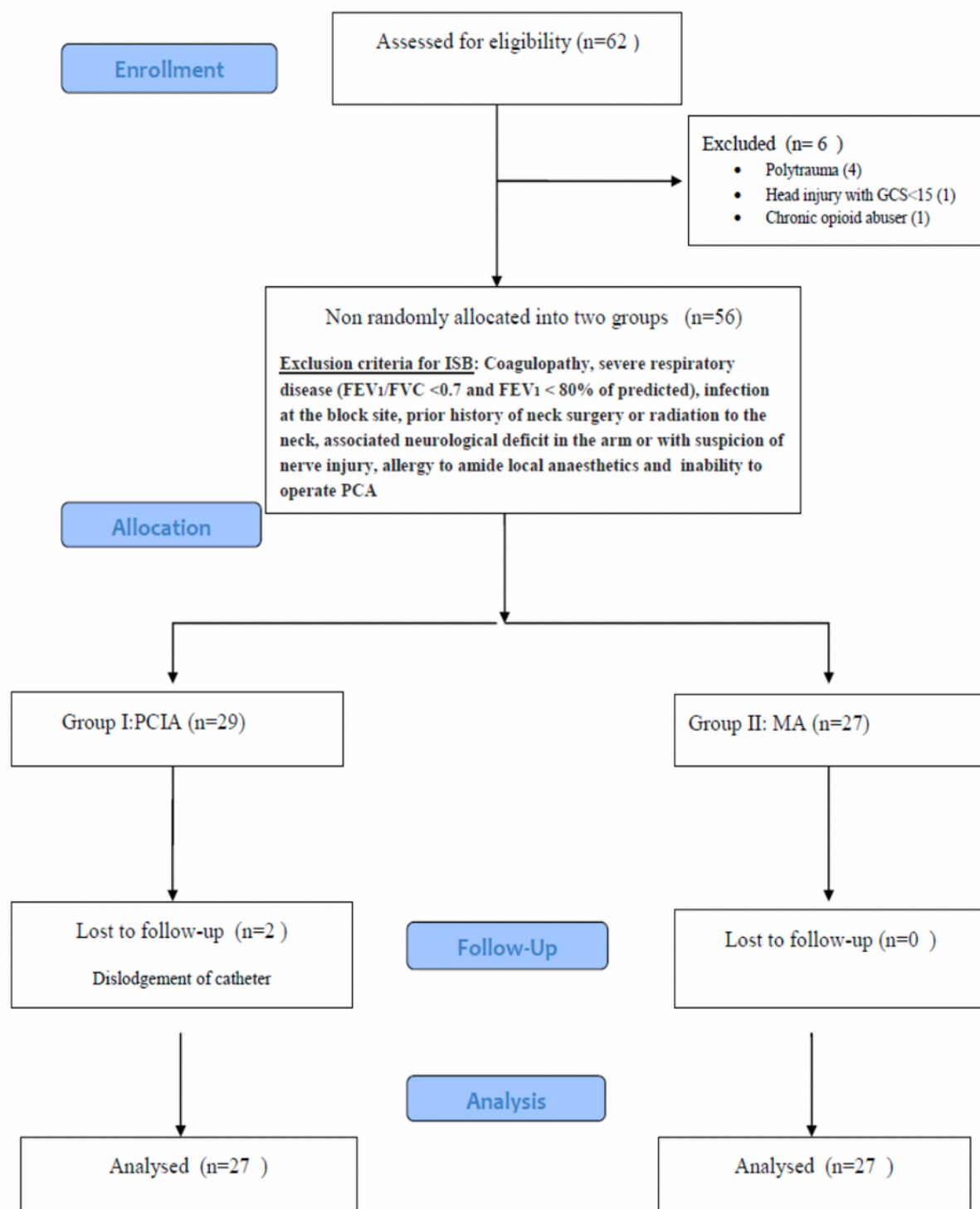


Figure 3

Study Flow Diagram